

## **REMARKS**

Claims 38-44, 46, 47, 49-52 and 54-64 are pending in the instant application. Claims 38 and 49 have been amended. Support for the amendments to claims 38 and 49 can be found, for example, page 3, lines 15-19 and 34-36, page 31, lines 26-36, page 32, lines 8-13, page 35, lines 21-26, page 37, lines 5-13, page 39, lines 26-33 and Figures 9 and 11 of the instant specification. Claims 54-62 have been added. Support for claims 54-64 can be found, for example, in claims 38-42, 44, 47 and 49-52 as previously presented, in Figures 12-14, page 7, lines 2-4, of the instant specification. Claims 45, 48 and 53 have been canceled. Applicants reserve the right to pursue these claims in a continuation application. No new matter has been added.

### **Claim Rejections**

#### **Rejections under 35 U.S.C. § 112, second paragraph.**

The Examiner has rejected claims 38-53, on page 3 of the Office Action, under 35 U.S.C. § 112, second paragraph, for indefiniteness for reciting the term “enhancing”. Claims 45, 48 and 53 have been canceled, thus this rejection is moot as it applies to these claims. The Examiner asserted that there is no reference to any type of comparison for the enhancement.

Applicants have amended claims 38 and 49, from which claims 39-48 and 50-53 depend, to specify that the comparison is to the lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against an infectious disease after administration of the vaccine alone. Applicants respectfully submit that this amendment renders claims 38-44, 46, 47 and 49-52 definite, and that one of ordinary skill in the art would be able to ascertain the metes and bounds of these claims. Thus, Applicants request that this rejection be withdrawn.

#### **Rejections under 35 U.S.C. § 102.**

The Examiner has rejected claims 38-39, 43-45 and 49, on pages 4-7 of the Office Action, under 35 U.S.C. § 102(b) as being anticipated by Williams *et al.* WO 97/02045 (“Williams”). Claim 45 has been canceled, thus this rejection is moot as it applies to this claim. The Examiner argued that Williams inherently anticipated claims 38-39, 43-45 and 49 because something which is old does not become patentable upon discovery of a new property. Thus, the claiming

of a new use that is inherently present in the prior art does not necessarily make a claim patentable. Applicants respectfully traverse the rejection.

Anticipation by inherency still requires that the prior art reference disclose each and every limitation of the claim.<sup>1</sup> As the Examiner points out in the Office Action, a prior art reference may anticipate when the claim limitation or limitations are not expressly found in that reference are nonetheless inherent in it.<sup>2</sup> Furthermore, inherency is not necessarily conterminous with the knowledge of persons of ordinary skill in the art.<sup>3</sup> That is, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.<sup>4</sup>

Nevertheless, in order for a prior art reference to anticipate a claim under the principles of inherency the prior art reference must necessarily function in accordance with, or include, all claimed limitations in order to anticipate the claim.<sup>5</sup> A conclusion that a result or characteristic may be present in the prior art reference is insufficient, as provided by M.P.E.P. § 2112 as follows:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’ ” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). (emphasis in original).

Additionally, as stated in *Glaverbel Societe Anonyme v. Northlake Marketing & Supply Inc.*, (Fed. Cir. 1995):

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<sup>1</sup> See *Standard Havens Prods., v Gencor Indus., Inc.*, 953 F.2d 1360, 1369 (Fed. Cir. 1991).

<sup>2</sup> See *id.*; *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 630 (Fed. Cir. 1987).

<sup>3</sup> See *Titanium Metals Corp. v. Am. v. Banner*, 778 F.2d 775, 780 (Fed. Cir. 1985).

<sup>4</sup> See *In re Crish*, 393 F.3d 1253, 2004 U.S. App. LEXIS 26518, 14-15 (Fed. Cir. 2004) (citing *In re Spada*, 911 F.2d 705 (Fed. Cir. 1990), *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985), *In re Pearson*, 494 F.2d 1399 (CCPA 1974), and *In re Benner*, 174 F.2d 938 (CCPA 1949) for the proposition that “one cannot establish novelty by claiming a known material by its properties.”).

<sup>5</sup> See *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986).

Anticipation, however, requires identity of invention; the claimed invention, as described in appropriately construed claims, must be the same as that of reference, in order to anticipate. *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1267, 20 USPQ2d 1746, 1748 (Fed. Cir. 1991). See also *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) ('the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it'). (33 USPQ2d at 1498)(emphasis added).

Applicant respectfully submits that Williams fails to inherently disclose methods of claims 38-39, 43-45 and 49. Claims 38 and 49, from which claims 39-44, 46, 47 and 50-52 depend, specify that the enhancing of a lymphocyte mediated or immunoglobulin mediated immune response to a vaccine against an infectious disease must be performed in a subject in need thereof. No such subject, in need of enhancement of a lymphocyte or immunoglobulin mediated immune response to a vaccine against an infectious disease is taught by Williams. Williams does not teach each and every limitation of claims 38-39, 43-44 and 49, and thus cannot anticipate them, inherently or otherwise. Thus, Applicants respectfully request that this rejection be withdrawn.

The Examiner has also rejected claims 38-53, on pages 7-11 of the Office Action, under 35 U.S.C. § 102(b) as being anticipated by Hazama *et al.* Immunology 78:643-649 (1993) ("Hazama"). Claims 45, 48 and 53 have been canceled, thus this rejection is moot as it applies to these claims. The Examiner argued that the features that Applicants relied on in arguments in their previous response were not recited in claims 38-53.

Applicants have amended claims 38 and 49, from which claims 39-44, 46, 47 and 50-52 depend, to specify that the vaccine be co-administered with the EtxB. Hazama only teaches the co-administration of EtxB (LTB) with tg-D, which is not a vaccine. As explained in the previous Office Action, the Board of Patent Appeals and Interferences has stated that, "a vaccine must by definition provoke an immunoprotective response upon administration."<sup>6</sup> The Board's definition is supported by other definitions in the art, for example, "[A]ny preparation used as a preventive inoculation to confer immunity against a specific disease, usually employing an innocuous form of the disease agent, as killed or weakened bacteria or viruses, to stimulate antibody

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<sup>6</sup> In re Wright, 999 F.2d 1557, 1561

production.”<sup>7</sup> The term “vaccine” is defined in *Microbiology, Fourth Edition* (Tortora, Funke, and Csaes eds, The Benjamin/Cummings Publishing Company Inc, 1992, pages 450-451),<sup>8</sup> as follows:

A vaccine is a suspension of microorganisms (or some part or product of them) that will induce immunity in a host. (Emphasis added).

In *Biology, Third Edition* (Arms & Camp eds., Saunders College Publishing, 1987, pages 713-714),<sup>9</sup> provides as follows:

Vaccination against a specific disease produces a primary immune response and thereby creates an immunological memory, ready to trigger an efficient secondary response at the body’s first real battle against the disease antigen.

Thus, as evidenced by the above citations, a person of ordinary skill in the art would understand the terms vaccine, or vaccination, to be used to describe a preparation, or the administration thereof, used as a preventive inoculation to confer immunity against a specific disease.

Hazama only teaches the co-administration of tg-D with EtxB. Hazama teaches that tg-D is not a vaccine. tg-D does not produce protective immunity in BALB/c mice infected with HSV.<sup>10</sup> The Examiner submits that the data in Tables 2 and 4 of Hazama are not relevant to the Applicants arguments because they do not exemplify the instantly claimed invention. Applicants respectfully disagree. Tables 2 and 4 demonstrate the tg-D is not a vaccine. Claims 38-44, 46, 47 and 49-52 require the co-administration of a vaccine. Hazama only teaches the co-administration of EtxB with tg-D and no other substance. Thus, Hazama does not teach the co-administration of EtxB with a vaccine. Hazama does not teach all of the features of claims 38-44, 46, 47 and 49-52 and cannot anticipate them. Applicants respectfully request that this rejection be withdrawn.

### **Rejections under 35 U.S.C. § 112, second paragraph.**

The Examiner has also rejected claims 38-53, on pages 11-13 of the Office Action, under 35 U.S.C. § 112, first paragraph, for lack of written description for adding new matter to the claims. Claims 45, 48 and 53 have been canceled, thus this rejection is moot as it applies to

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<sup>7</sup> Random House Unabridged Dictionary, © Random House, Inc. 2006.

<sup>8</sup> The relevant portion of which was previously provided as Exhibit A.

<sup>9</sup> The relevant portion of which was previously provided as Exhibit B.

<sup>10</sup> See Hazama at pages 646-647 Table 2.

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these claims. The Examiner argued that there was no support for “enhancing the leukocyte mediated immune response”. Applicants have amended claims 38 and 49, from which claims 39-44, 46, 47 and 50-52 depend, to replace “leukocyte” with “lymphocyte”. As pointed out by the Examiner, on page 12 of the Office Action, the instant specification teaches methods for enhancing the levels of T-cells and B-cells, both types of lymphocyte. Thus, Applicants respectfully submit that claims 38-44, 46, 47 and 49-52, do not present new matter and request that this rejection be withdrawn.

### **CONCLUSION**

Applicants submit that the claims as here amended put the application in condition for allowance, and such action is respectfully requested. Should any questions or issues arise concerning the application, the Examiner is invited and encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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